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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,781	08/28/2006	Rolf Muller	0112843-001 - 91905 US	5896

24573 7590 09/21/2009

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EXAMINER	
ANDERSON, JERRY W	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
09/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,781	MULLER ET AL.	
	Examiner	Art Unit	
	JERRY W. ANDERSON	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/31/2009 has been entered.

Response to Amendment

2. Claims 1, 3, 5-15, are amended and claims 16-17 are new.

3. Applicant having amended claims 8 and 10 to address issues under 35 USC 112, said rejections thereunto are withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 1,3 and 5-17, are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi Y-C., et at., (6,890,571) in view of Haralampu, S.G., et al. (5, 849,090)**

7. Shi ('571) discloses:

a. resistant, gelatinized, crystallized starch, (lines 6-9 col. 3, lines 34-35, 46-48 col. 4, '571)

b. resistant to digestion in the small intestine, and passes into the large intestine, (line 13-15 col. 1, '571)

c. sample 1B 22.7 at 20 min, 48.6 at 120 min, (table 1, '571)

d. sample 1D 25 at 20 min, 50.3 at 120 min, (table 1, '571)

e. A slowly digestible starch product prepared by enzymatically debranching low amylose starches and allow the resultant linear short chains to crystallize to a highly crystalline form, (lines 20-25, col. 2, '571)

f. starch made be used in a variety of edible products . . . cereal, bars . . . dietary supplements, (lines 29-41, col. 5, '571)

8. Haralampu ('090)discloses:

g. Increased fecal bulk . . .increased excretion of butyrate and acetate [in the colon] (lines 25-28 col. 1, '090)

h. Slow hydrolysis of resistant starch . . . controlling glycemic plasma responses, (lines 34-37 col. 1, '090)

i. The granular resistant starch . . . co-processed with hydrocolloids, polymers, gums, modified starches . . . to change the functional properties, (lines 33-38 col. 2, '090)

j. Particularly preferred starches are high amylose starches, most preferable starches containing at least 30 % amylose, (lines 28-31, col. 3, '090)

k. granular resistant starch . . . can be used as a dietary fiber supplement . . . as a tabletting aid, (lines 20-27, col. 6, '090)

l. Batch co-processed with hydrocolloid sodium carboxymethyl cellulose . . . added on a 10 % basis relative to the starch, (lines 14-18, col. 8, '090)

9. Regarding Claim 1 and 8, the Applicant claims a slow digestible starch product, with a swellable network, crystallites and an initial hydrolysis rate of <300 %/h. *Shi* teaches a resistant, gelatinized, crystallized starch, (lines 6-9 col. 3, lines 34-35, 46-48 col. 4, '571) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, (line 13-15 col. 1, '571) The applicant determines the hydrolysis rate by measuring the amount of undigested starch at intervals of .5, 1, 2, 3, 4, 5, and 6 hours and calculating the digested portion of the starch. This data is shown in Table 1 and plotted in Figures 1-5, (applicant's specification) Applicant states that *Shi*'s data is

comparable to amylase treated cornstarch, with a Ho of 200 %hr, Hc of 200 %/hr and a Tc of 0.25 hours. (¶ 46, Table 1, Applicant) However, comparison of the data in Shi's Table 1, samples 1B and 1D, the % digested values at 20 min and 120 minutes, which are approximately 24 % and 49 %, (table 1, '571) respectively with the applicant's data yields different results. Said data when plotted on the applicants graph in Fig. 3, are similar in performance, if not slightly better than the results of samples WS 72-2 through 4, which have Ho (%/h) of 70-90, Hc (%/h) of 20-22 and Tc (h) of 2.5. When compared with Fig. 4, the values of Shi's samples 1B and 1D appear to be almost identical to the data points of Sample WS-55-3, which has a Ho of 54, Hc of 16 and a Tc of 2.5 hours. One of ordinary skill in the art would find it obvious that Shi's samples 1B and 1D, exhibiting similar values when compared to the aforesaid applicant data would have similar results to the Ho, Hc and Tc values of the applicant's samples. Therefore, interpolation of the applicant's data would yield for Shi's samples 1B and 1D an estimated value of about, Ho: 54-90 (%/h), Hc: 14-22 (%/h) and Tc: 2.5 hours. A process of manufacturing a slowly digestible starch product prepared by enzymatically debranching low amylose starches and allow the resultant linear short chains to crystallize to a highly crystalline form, (lines 20-25, col. 2, '571) with an initial hydrolysis rate of less than 300 %/h. (pg 46, Table 1, Applicant) and a Tc of at least 0.5 hours. However, Shi lacks the use of a starch containing greater than 20 % amylose content. Haralampu teaches the use of starches containing at least 30 % amylose, (lines 28-31, col. 3, '090)

10. *Shi* and *Haralampu* are analogous art in that both are concerned with the modification of starches to form a slowly digestible starch.

11. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the methods of *Shi* by the use of starches containing more than 30 % amylose starches, (lines 28-31, col. 3, '090), to produce physiological benefits of fiber, such as increased fecal bulk, and increased excretion of butyrate and acetate in the colon. (lines 25-28 col. 1, *'090*).

12. **Claims 3, 5-7, and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi Y-C., et at., (6,890,571) in view of Haralampu, S.G., et al. (5, 849,090), for the reasons stated in the office actions mailed 11/28/08 and 6/03/2009 and are incorporated herein.**

13. **Regarding Claim 16,** Shi and Haralampu disclose, as discussed above, a process of manufacturing a slowly digestible starch product prepared by enzymatically debranching low amylose starches and allow the resultant linear short chains to crystallize to a highly crystalline form, (lines 20-25, col. 2, '571) with an initial hydrolysis rate of less than 300 %/h. (pg 46, Table 1, Applicant) and a Tc of a least 0.5 hours.

14. **Regarding claim 17**, Shi and Haralampu disclose the claimed invention, as discussed above, but lacks the use of a tablet. Haralampu discloses granular resistant starch which can be used as a dietary fiber supplement and as a tabletting aid, (lines 20-27, col. 6, '090) One of ordinary skill in the art would find it obvious that using the granular starch product as a tabletting aid would result in the formation of tablets containing said starch product.

Response to Arguments

15. The applicant having amended claims 1 and 8 to include the term starch with amylose content greater than 20 %. Shi does not teach the use of a starch with amylose greater 20 %, however, Haralampu does teach the use of a starch with amylose content greater than 30 %. When used in combination, Shi and Haralampu meet all the elements of the amended claims.

16. Applicant's arguments with respect to claims 1, 3, and 5-17, have been considered but are moot in view of the new ground(s) of rejection. Applicant's traversals of the references are based entirely on the new limitations added to the claims by the amendment filed, now deemed moot by the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY W. ANDERSON whose telephone number is (571)270-3734. The examiner can normally be reached on 7 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/
Primary Examiner, Art Unit 1794

jwa